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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 19/00, G01F 17/00, A61B 5/107 — A1

(11) International Publication Number: **WO 95/26689**

(43) International Publication Date: 12 October 1995 (12.10.95)

(21) International Application Number: PCT/IB95/00042

(22) International Filing Date: 19 January 1995 (19.01.95)

(30) Priority Data:
08/221,309 31 March 1994 (31.03.94) US

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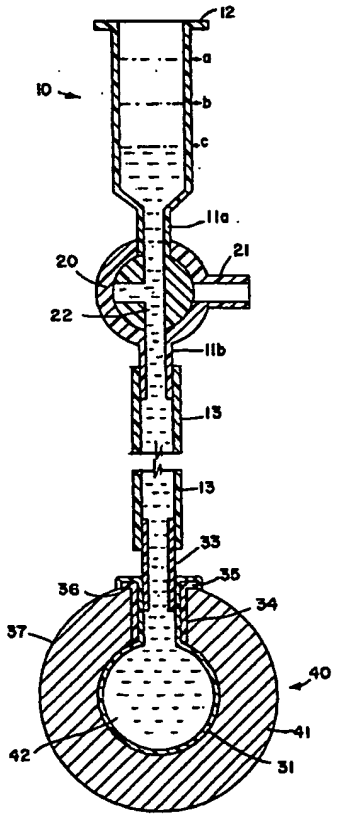
(81) Designated States: CA, DE, JP, MX, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: MEASUREMENT OF NUCLEOUS MATERIALS REMOVED DURING DISCECTOMY

(57) Abstract

A method for determining the volume of the cavity (42) left in an intervertebral disc (40) after surgical removal of the nuclear material therefrom which consists of inserting a deflated flexible expandable container (31), of known volume, thereinto: filling said container (31) with a liquid (L), from a calibrated source (10) of said liquid (L), and causing the container (31) to expand until it completely fills the cavity (42); determining the volume of liquid (L) required to cause the container (31) to completely fill the cavity (42) and calculating the volume of the cavity (42) which is equal to the sum of the volume of liquid (L) required to fill the deflated flexible expandable container (31) and the volume of deflated container (31) itself. A method for determining the shape of the cavity (42) which comprises adding a contrast composition to the liquid (L) in the above method and placing the disc (40) in an imaging apparatus. An apparatus for determining the volume of the cavity (42) left in an intervertebral disc (40) after surgical removal of the nuclear material therefrom which comprises a deflated flexible expandable container (31), a calibrated source (10) of liquid (L) to expand the container (31) and connector means (33) to provide fluid connection between the container (31) and liquid source (10). An apparatus for determining the shape of the disc (40) wherein the above apparatus further comprises a contrast composition added to the liquid (L) and an imaging apparatus.



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MEASUREMENT OF NUCLEUS MATERIALS REMOVED DURING DISCECTOMY

This invention relates to intervertebral discs. More particularly, it relates to a method and apparatus for determining the amount of nuclear material removed from said disc during, and the shapes of the cavity created after lumbar surgery.

The normal intervertebral disc has an outer ligamentous ring called the annulus which binds the adjacent vertebrae together and is constituted of collagen fibers that are attached to the vertebrae and cross each other so that half of the individual fibers will tighten as the vertebrae are rotated in either direction, thus resisting twisting or torsional motion. Torsional movement between vertebral segments is further restricted by the facet joints.

Deep inside the annulus lies a nucleus pulposus of loose tissue which is slippery and slimy (having about 70-75% water content) and moves about during bending from front to back or from side to side. Thus, as the opposing surfaces of the vertebrae alter their parallel relationship to each other with bending, the nuclear tissue moves about to fill up the change in distance (wedging) that occurs in the opposing ends of the disc space. With bending, the annulus will bulge on the downward wedged side and be stretched tightly on the upward wedged side.

A classical disc herniation occurs when the annular fibers are weakened or torn and the inner tissue of the nucleus becomes permanently bulged, distended, or extruded out of its normal annular confines. Leg pain in such case results from this nuclear tissue (or an intact weakened, bulging annulus) compressing a nerve which passes outward from the spinal canal to the leg.

A major cause of persistent, disabling back pain takes place when the annulus becomes chronically inflamed by a degenerative process. Small nerves that come from branches encircling the outside of the annulus penetrate for a short distance (perhaps 6 to 8 mm) into the annular fibers. Constant abnormal motion between the fiber layers of the annulus, due to loss of bonding between them, may stretch and grind the tiny pain fiber nerve endings. Thus the patient becomes sensitive to the slightest movement. These cases require some form of mechanical limitation to intervertebral disc motion at the painful segment. For the most persistent cases, bony fusions are often performed to stop the painful motion by permanently locking the vertebrae together. In many cases it may be preferred to allow some minor movement (less than

that which causes the pain). Preserving some movement helps to prevent mechanical breakdown at nearby segments. At present, to attempt to make and maintain these flexible fusions is not reliably feasible.

One of the major treatments for low back pain (or leg pain), caused by a herniated disc, is discectomy surgery in which part or all of the nucleus material is removed. The major purpose of removing the nucleus material is decompression - i.e., relief of the compression of the nerve caused, directly or indirectly, by the nucleus. There are many surgical techniques used to remove nucleus material, such as open surgery, Microdiscectomy (e.g., Arthroscopic MicroDiscectomy), serdiscectomy and Automated Percutaneous Lumbar Discectomy. Since the amount of removed nucleus can directly affect the intradiscal pressure of the disc and the overall results of the discectomy surgery, it is desirable to know how much nucleus has been removed from the disc during the discectomy.

Although discectomy has a high rate of success in alleviating primary symptoms, e.g., low back or leg pain, it often causes disc narrowing and increase of disc mobility which may again cause back pain at a later stage. U.S. Patent 5,047,055 (assigned to the same assignee as this application and incorporated herein by reference) describes a prosthetic disc nucleus implant which overcomes this limitation. Since the disc nucleus implant will be used to occupy all the cavity space created in the discectomy surgery it is important to know and control the cavity size and shape. Therefore, it is necessary to have a method and apparatus to measure the discal cavity size and shape during the surgery.

Capanna et al. (Spine, 6, 610-614 [1981]) described a method for measuring the "percentage of disc removal" during lumbar discectomy using discograms and lumbosacral radiographs. However, this method does not provide a simple way to give the volume and is unable to define the shape of the cavity. Furthermore, it is subject to relatively large errors.

Other methods for estimating the amount of nucleus removed during or after discectomy surgery have been discussed in the literature. One method often used, especially for cadaveric discs, is to collect all of the removed nucleus materials and weigh them directly on a balance. However, it is difficult to be sure that all the nucleus materials have been collected and to weigh them during the operation. Furthermore,

since the nucleus materials have been either mixed with saline solution or evaporated and then sucked out from the disc, in Automated Percutaneous Lumbar Discectomy and Laser Discectomy techniques, the weight of the removed nucleus material can not be obtained directly. Another way of measuring the nucleus of the material weight, especially in Automated Percutaneous Lumbar Discectomy, is to install a filter in the suction tube, separate the nucleus material from the flushing solution and then weigh the nucleus material. However, the nucleus material tends to absorb fluids resulting in a weight change after it has been removed from the disc. This method does not give an accurate measurement.

SUMMARY OF THE INVENTION

It is an object of this invention to provide a method for directly determining the volume of nuclear material removed during a discectomy which comprises inserting a deflated flexible expandable first container into the cavity left in the disc after said removal, adding a liquid to the container to cause it to expand until it fills the cavity and determining the amount of liquid required to so expand the container.

It is yet another object to provide a method for determining the shape of the cavity by adding an indicating material to said liquid to allow the image of said cavity to be viewed in an imaging apparatus.

Another object of the invention is to provide an apparatus for use in determining the amount of nuclear material removed from a disc during a discectomy which comprises a flexible expandable first container, a liquid and a calibrated container for said liquid in fluid connection with said first container.

Yet another object of the invention is to provide an apparatus, as described above, wherein said calibrated container comprises syringe means comprising a hollow tube, comprising an opening at each and thereof, to contain said liquid and means to cause the liquid contained in the tube to be injected into the second container means.

Another object of the invention is to provide an apparatus, as described above, wherein said filling means comprises a flexible, collapsible bulb which is caused to collapse by the application of pressure applied to the outer walls thereof wherein the liquid, contained in said tube is injected into the first container to which it is fluidly connected, and causes the first container to expand.

According to another object of the invention there is provided an apparatus, as described above, wherein said filling means comprises a syringe, comprising a

calibrated barrel and an axially and reciprocally movable plunger inserted therein or the combination of a pipette with means to cause liquid contained therein to be expelled therefrom.

Another object of the invention is to provide an apparatus, as described above, wherein said means to cause the liquid to be expelled from the pipette comprises a flexible, collapible bulb.

Yet another object of the invention is to provide an apparatus for use in determining the shape of the cavity in a disc after removal of nuclear material therefrom comprising a flexible expandable first container, a liquid and a calibrated second container for said liquid in fluid connection with said flexible expandable container wherein said liquid contains a composition which allows the shape of the container holding said liquid to become visible in an imaging apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A is an elevational section view of the apparatus of a first embodiment of the invention.

Figures 1B-1D are sectional views showing various positions of the bore of the valve means of the apparatus of Figure 1A.

Figure 2 is a top plan view of an intervertebral disc with its nuclear material removed and a hole through one wall of its annulus.

Figure 3 is an elevational sectional view of the disc of Figure 2.

Figure 4 is an elevational sectional view of the apparatus of Figure 1A set up for calibration.

Figure 5 is an elevational sectional view of the apparatus of Figure 1A set up for measurement of the volume of the nuclear cavity of an intervertebral disc.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENT

Referring to Figure 1A the apparatus of the invention, designated by the numeral 1, comprises a calibrated second container 10 comprising an opening 12 at one end and an outlet stem 11 at the other end. Container 10 further comprises injection means to cause the liquid to flow from said container when pressure is applied to said injection means. Outlet stem 11 comprises a distal portion 11a adjacent the barrel of the container and a proximal portion 11b separated from the distal portion by valve means 20. The valve means may be 2- or 3- way valves. The outlet stem portion and valve may be unitary (as shown) or comprise two or more parts joined by connecting means.

The upper, open portion of a flexible, expandable first container 31 (a balloon in the illustration) is stretched and draped over the flange 35 of an outer tube 34. An inner tube 33 is inserted into the mouth of the balloon 31 until its proximal end passes the distal opening in outer tube 34. The outer diameter of the inner tube 33 and inner diameter of the outer tube 34 are so selected that the wall of balloon 31 is held tightly between them. Flange 35 may be an integral part of tube 34 or may comprise a separate ring axially movable along the outer wall of tube 34.

Inner tube 33 is fluidly connected to valve means 20 through connecting tube 13 which is attached to the distal end of inner tube 33 and the outlet stem portion 11b.

A disc, the volume of whose nuclear cavity is to be determined by the method of the invention, is illustrated in Figures 2 and 3 and designated by the numeral 40. The disc comprises a fibrous annulus 41 and a cavity 42 from which the nucleus material has been removed in the surgeon's usual manner, e.g., curettage and microdiscectomy with pituitary forceps. The disc further comprises a longitudinal hole 43, extending from the outer wall 37 to the cavity, through which the nuclear material has been removed.

In the operation of the invention the volume of the apparatus between valve means 20 and the proximal end of outer tube 34 is determined as follows. The initial volume of liquid L in container 10 is obtained from the marking a thereon. The bore 22 of valve means 20 is turned to the position shown in Figure 1B and vacuum applied through stem 21 whereby balloon 31 is evacuated and collapses. The bore 22 of the valve means is then turned to the position shown in Figure 1D and liquid L is allowed to flow from container 10 through bore 22 and connecting tubes 13 and 33 into first container 31. Container 31 expands, filling the cavity in outer tube 34 until the proximal end 39 of the expanded balloon is flush with the proximal opening 44 of outer tube 34. A reading, **b**, is taken of the volume of liquid L in container 1. The difference between **a** and **b** is the volume of the measuring apparatus between valve means 20 and the proximal end 39 of expanded balloon 31.

The outer tube 34 of the apparatus 1 is then inserted into hole 43 of the disc 40 until the inner surface 36 of flange 35 of the outer tube abuts the outer wall 37 of the disc. The length of outer tube 34 is so chosen that it does not extend into the cavity 42 formed upon removal of the nuclear material from the disc. Liquid L is allowed to continue to flow until the expanded balloon fills the cavity 42 of the disc. A reading is

then taken of the volume c in container 1. The difference between b and c is the volume of the cavity 42 in the disc.

The filling means comprises

a) rigid second container means, to contain the liquid, which comprise a barrel comprising open proximal and distal ends;

b) pressure means, at the proximal end of the barrel, to apply pressure to the liquid and force it to flow out of the barrel at the distal end thereof.

Filling means for use in the practice of this invention include syringes wherein

a) the second container means comprises a pipette (e.g., catalog number 13-678, Fisher Scientific, Pittsburgh, PA 15219) and the pressure means comprises a bulbs or dispensers (e.g., catalog numbers 13-681-15, 13-681-50, 13-681-61 and 14-070, ibid). If a dispenser such as 13-681-15, which is electrically powered, is used it will be necessary to use a pressure controller therewith; or

b) the second container means comprises a cylindrical barrel, disposed about a longitudinal axis and the pressure means comprises plunger means, which is inserted through the proximal opening of the barrel, and is axially and reciprocally movable therein (such a combination is, e.g., a syringe such as catalog number 14-823-10, ibid).

Preferred filling means are syringes (such as catalog number 13-578, above) of about 5 to about 10 ml capacity.

The materials of construction for use in the invention are biocompatible materials such as plastics and metals. The materials of construction must also be compatible with the measuring liquids.

The first container may be made from any physiologically compatible elastic material such as natural, synthetic, silicone or polyurethane rubbers.

Liquids, L, for use in the practice of the invention include water and aqueous solutions of pharmaceutically acceptable salts (e.g., saline).

It is sometimes desirable to ascertain the shape, as well as the volume, of cavities formed in intervertebral discs during discectomy. This can easily be accomplished using another embodiment of this invention wherein the liquid L comprises a contrasting composition which causes the cavity to become visible in an imaging device. Such indicating compositions include both oil-based and water-based media such as iophendylate, meglumine iothalamate, diatriazoate meglumine and

Renogatrin (trademark) mixed with methylene blue. Water-based compositions are preferred. Such imaging devices include computed tomography (CT) scanners and magnetic resonance imaging (MRI). A preferred imaging device is a CT scanner and a most preferred liquid is 30% aqueous Renogatrin containing methylene blue.

Alternatively, the apparatus can be calibrated as follows:

Outer tube 34, of the apparatus is inserted into a receiving container, designated 2 and shown in Fig. 4, until a marking thereon indicating a known volume V. The initial volume a in container 1 is recorded. Valve 20 is turned so that the bore thereof is in the position shown in Figure 1B. Vacuum is applied to the apparatus, from a vacuum source (not shown), through stem 21 of the valve, whereby the balloon 31 is evacuated and deflated.

The bore 22 of valve 20 is then turned until it assumes the position shown in Figure 1D at which time the liquid L flows from container 1 into the balloon through the valve and connecting tubes 13 and 33. As the balloon fills with the liquid it expands until it fills the whole empty space of the receiver 2. The volume b in the container 1 is read and the total volume, V_T, of the apparatus, proximally from valve means 20, and receiver is calculated as follows:

$$V_T = a - b.$$

The volume of the apparatus, V_A without the receiver, is then:

$$V_A = V_T - V.$$

In use the length of outer tube 34 will be so chosen that its proximal end does not extend beyond the inner wall of the annulus. The volume of the apparatus must then be recalculated to take into consideration any differences in volume caused by a change in the tube's length. The new volume V'_A of the apparatus is given by

$$V'_A = V_A + \tfrac{1}{4}\pi D^2 l$$

wherein D is the inner diameter of outer tube 34 and l, which may be positive or negative is the change in length of the outer tube.

The receiver 2 is then removed from the outer tube 34 and the balloon drained and deflated through valve stem 21 of valve 20. Outer tube 34 with its associated balloon 31 and inner tube 33 are then inserted into the disc 40 through hole 43, as described above. Container 10 is filled with liquid L until the level a and the volume

corresponding to that level is recorded Valve 20 is opened to the position shown in Fig. 1D and the liquid flows into the balloon causing it to expand and fill cavity 42 of disc 40. The volume of liquid in container 10 drops to the level c and the volume corresponding thereto is recorded. The volume V'_T of the apparatus and cavity from volume 21 is given by b - c. The volume of the disc is then given by $V'_T - V'_A$ wherein V'_A is determined as above.

Example

A). Apparatus and Assembly.

The measuring device consists of a 10 ml syringe (Reorder number 9604, Becton-Dickinson, Rutherford, NJ 07070) comprising a male Luer fitting at its distal end, a bidirectional stopcock (Catalog number G-06464-72, Cole-Palmer, Niles, IL 60714), a polypropylene extension tube and a small balloon. The bidirectional stopcock has a female Luer fitting at one end and a male Luer fitting at the other end. The female Luer fitting of the stopcock was connected to the syringe through its male Luer end. The extension tube was about 20 mm long, had an inner diameter of about 5 mm, an outer diameter of about 6 mm and a female Luer fitting at one end. The small balloon was inserted into the extension tube with the closed end of the balloon going into the Luer fitting side leaving some of the balloon outside of the tube. The open end of the balloon was then stretched and draped over the outside of the tube. Then the male Luer end of the stopcock was carefully inserted into the female Luer end of the extension tube with the balloon sitting inside of the tube until the tube is securely locked into the stopcock. The stopcock was turned to its open position and the plunger of the syringe was slowly drawn back to create a vacuum in the system. While the system was still under vacuum the stopcock was turned to the off position. The syringe was then disconnected from the stopcock which maintained the vacuum inside of the balloon. The syringe was charged with a known amount of saline without air in it and reconnected to the stopcock. The device was ready to use.

B). Device Calibration.

A cavity, of nucleus shape, was created in a plastic block through a cylindrical window of about 7 mm diameter and about 10 mm length. The exact volume of the cavity was measured by first weighing the empty plastic block and then weighing the block with the nucleus shaped cavity filed with water (not to the cylindrical window). The difference between these two weights was 4.2 gm. Since the density of water is

1, the volume of the cavity is 4.2 cc. The extension tube of the device of Part A was inserted into the cylindrical window and the tip of the tube was aligned with the end of the window. The initial volume of saline in the syringe, before opening the stopcock, was 9.2 cc. After opening the stopcock, the saline was injected into the balloon. The balloon expanded until the whole volume of the cavity was filled with the inflated balloon. At this point, it was almost impossible to inject more saline into the balloon. The volume of saline in the syringe was again determined and found to be 4.8 cc. The difference between the initial and final readings is the volume injected (4.4 cc). Since the volume of the cavity is 4.2 cc. Therefore, the device had a dead volume of about 0.2 cc which should be subtracted from the volume of liquid dispensed by the syringe in determining nucleus cavity volumes.

C). Determination of Disc Cavity Volume.

A discectomy was performed on a cadaveric lumbar disc using a pituitary rongeur. The nucleus materials which were removed during discectomy were carefuly collected and weighed. The weight of the removed nucleus material was found to be 2.4 g., which, assuming the density of the nucleus materials to be about 1, would correspond to a volume of about 2.4 ml. The volume of the cavity was then measured using the apparatus of section A. The volume of liquid, dispensed by the syringe, was 2.5 ml. The dead volume of the system, 0.2 ml as determined in section B, above, to yield a value of 2.3 ml as the volume of the cavity. This value corresponds, favorably, to the volume determined by weighing the removed nucleus materials.

The volumes of the excavated cavities of other cadaveric discs were determined by the above method. It was found that the directly measured volumes did not differ from the weights of the excavated nucleus materials by significant amounts. Generally the difference was less than about 0.2 cc. This accuracy is much better than any other methods and is good enough for most purposes.

The present invention is not limited to the described example. It is obvious that many changes and modifications may be made thereunto, without departing from the spirit and scope of the invention.

CLAIMS

1. A method for determining the volume of the cavity (42) left in an intervertebral disc (40) after surgical removal of the nuclear material therefrom which consists of inserting the distal end (39) of a deflated flexible expandable container (31), of known volume, thereinto: filling said container (31) with a liquid (L), from a calibrated source (10), of said liquid (L), and causing the container (31) to expand until it completely fills the cavity (42); determining the volume of liquid (L) required to cause the container (31) to completely fill the cavity (42) and calculating the volume of the cavity (42) which is equal to the sum of the volume of liquid (L) required to fill the deflated flexible expandable container (31) and the volume of deflated container (31) itself.

2. The method of claim 1 wherein said liquid is water.

3. The method of claim 1 wherein said liquid is normal saline.

4. The method of claim 1 wherein said first container is a balloon.

5. The method of claim 1 wherein the source (10) of said liquid (L) is a syringe.

6. The method of claim 1 wherein said physiologically compatible elastic composition is selected from the group consisting of natural, synthetic, silicone and polyurethane rubbers.

7. The method of claim 1 wherein said liquid further contains an indicating composition to allow the shape of the cavity to be seen in an imaging apparatus.

8. The method of claim 7 wherein said indicating composition is selected from the group consisting of iophendylate, meglumine iothalamate, diatriazoate meglumine and Renogatrin (trademark) mixed with methylene blue.

9. The method of claim 8 wherein aid indicating composition is 30% aqueous Renogatrin containing methylene blue.

10. The method of claim 7 wherein said imaging apparatus is a CT or MRI scanner.

11. The method of claim 11 wherein said indicating composition is 30% aqueous Renogatrin containing methylene blue and said imaging apparatus is a CT scanner.

12. An apparatus for determining the volume of the cavity (42) left after nuclear material has been removed from an intervertebral disc (40) during a discectomy comprising

a) a flexible, expandable first container (31) capable of being expanded, by a fluis injected thereto, to fill said cavity (40) wherein said first container (31) comprises a physiologically compatible elastic composition; and

b) a source (10) of said liquid (L) in fluid connection with said flexible, expandable first container (31).

13. The apparatus of claim 12 further comprising valve means (20) interposed between said flexible, expandable first container (31) and said calibrated second container (10).

14. The apparatus of claim 12 wherein the source of liquid (L) is a syringe.

15. The apparatus of claim 12 further comprising a contrast composition to permit the shape of the cavity to be visualized in an imaging appratus.

16. The apparatus of claim 15 wherein said indicating composition is 30% aqueous Renogatrin containing methylene blue and said imaging apparatus is a CT scanner.

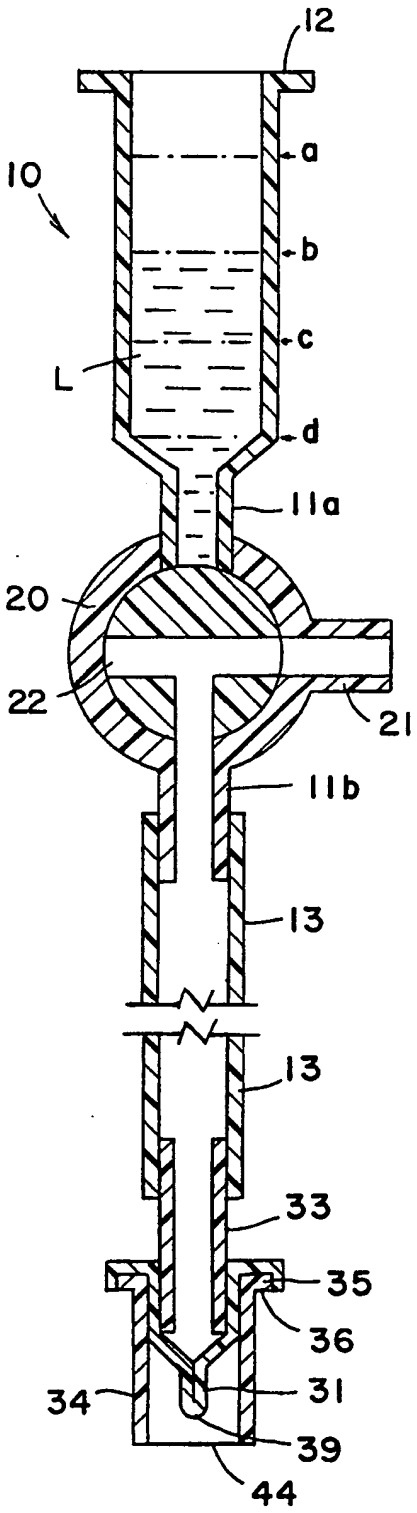


FIG. 1A

FIG. 1B

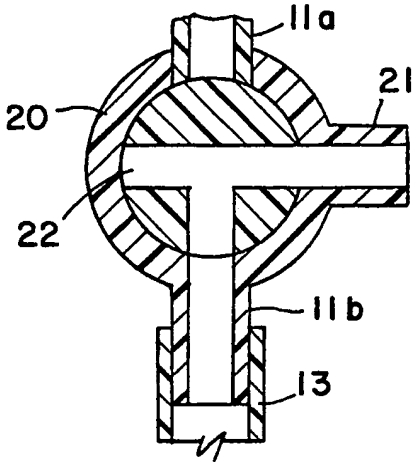
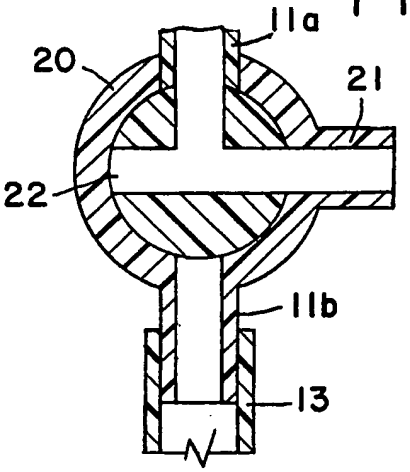


FIG. 1C



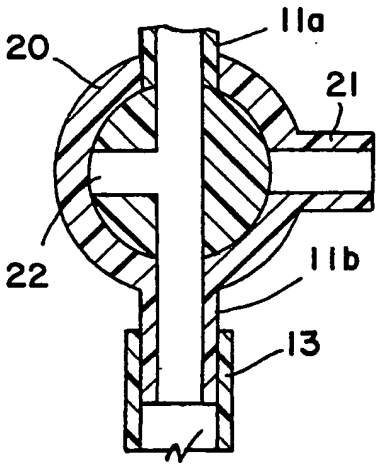


FIG. 1D

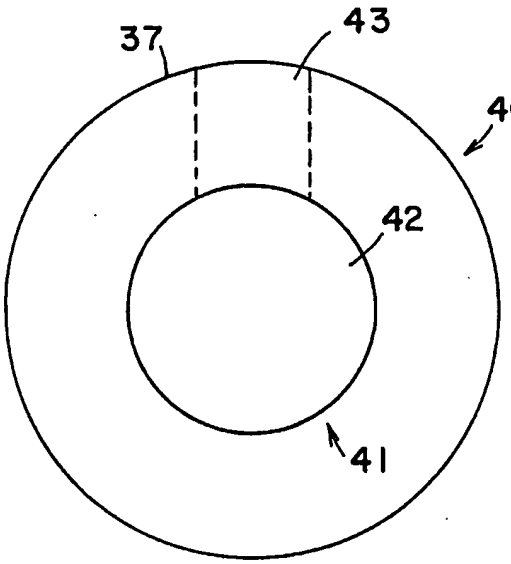


FIG. 2

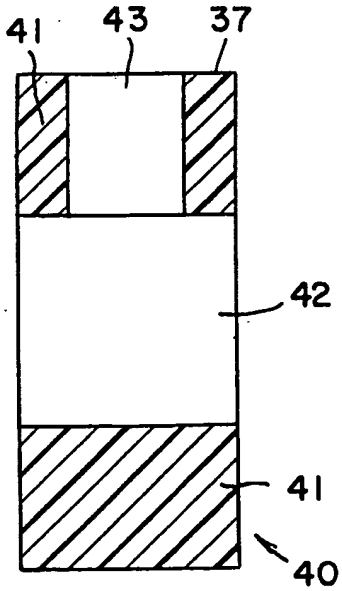


FIG. 3

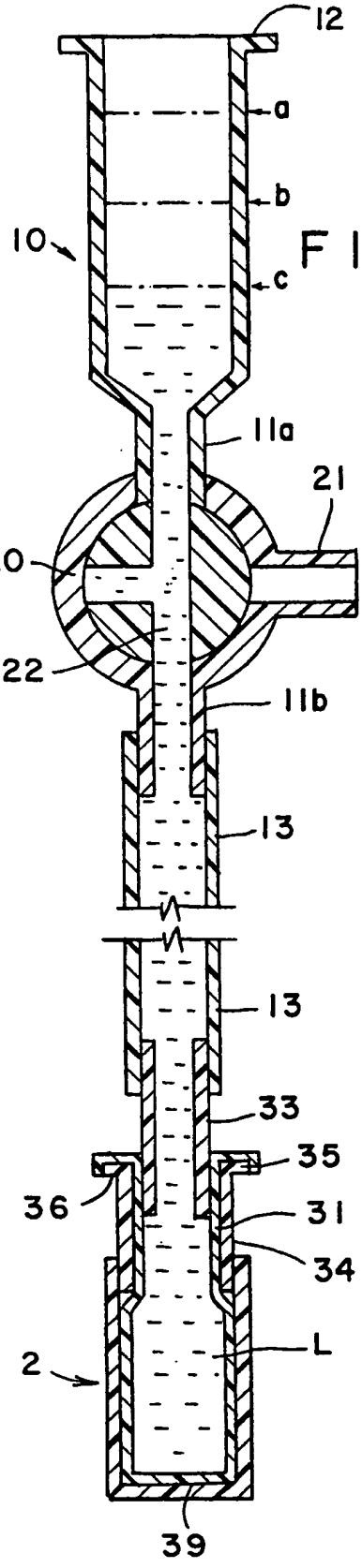
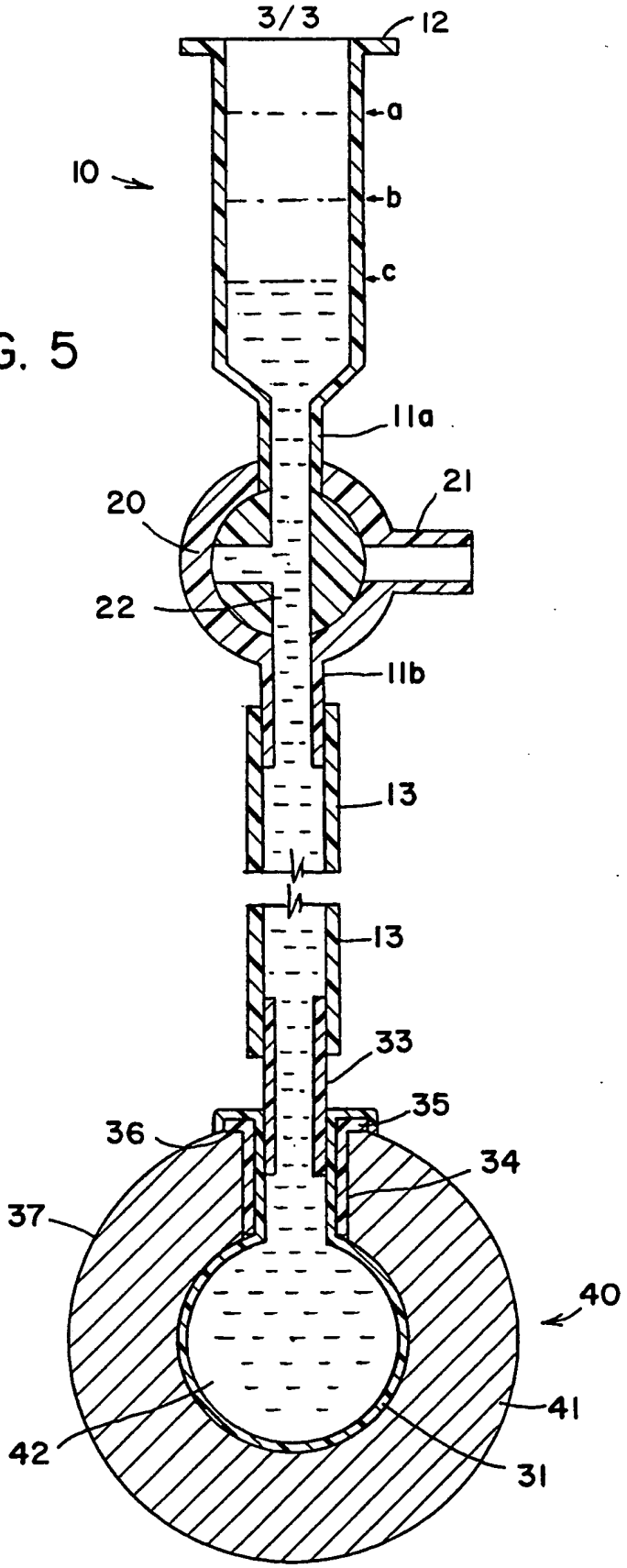


FIG. 4

FIG. 5



INTERNATIONAL SEARCH REPORT

Inter mal Application No
PCT/IB 95/00042

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B19/00 G01F17/00 A61B5/107

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B G01F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US-A-4 955 905 (REED) 11 September 1990 see abstract; figures	12-14
A	EP-A-0 364 966 (TOKYO SHIBAURA ELECTRIC) 25 April 1990 see abstract; figures	15,16

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
21 August 1995	07.09.95
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Authorized officer Hagberg, A

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter ...nal Application No
PCT/IB 95/00042

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-4955905	11-09-90	NONE		
EP-A-364966	25-04-90	JP-C-	1791241	29-09-93
		JP-A-	2109546	23-04-90
		JP-B-	4081455	24-12-92
		US-A-	5018173	21-05-91